

### **INTRODUCTORY COMMENTS**

Claims 217-229, 240-244 and 250-270 were pending in the subject application for the non-final Office Action dated February 19, 2009. Each of the pending claims currently stands rejected. In view of the following remarks, reconsideration and allowance of the subject application are hereby requested.

## **REMARKS**

### **Claim Rejections – 35 USC § 102**

Claims 217-229, 240-244, 250-258 and 261-270 have been rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 7,048,762 to Sanders et al.

### **Declaration of Prior Invention in the United States Under 37 C.F.R. §1.131**

The '762 patent was filed on August 20, 2001 as a national stage application stemming from International PCT Application Serial No. PCT/US98/17769 filed on August 27, 1998 (hereafter "the '769 PCT application"), which in turn purports to claim priority as a continuation-in-part of U.S. Patent Application Serial No. 08/920,630 filed on August 27, 1997 (hereafter "the '630 parent application").

The subject application is a continuation of U.S. Patent Application Serial No. 10/645,413 filed on August 21, 2003, which is a continuation of U.S. Patent Application Serial No. 09/698,623 filed on October 27, 2000 (now U.S. Patent No. 6,610,065), which is in turn a divisional of U.S. Patent Application Serial No. 09/181,353 filed on October 28, 1998 (now U.S. Patent No. 6,174,311). Accordingly, the subject application has an effective priority date of October 28, 1998. Additionally, absent the purported priority claim to the '769 PCT application and the '630 parent application, the '762 patent does not constitute prior art to the subject application.

Additionally, the Applicants submit herewith a Declaration of Prior Invention under 37 C.F.R. §1.131 to remove the '769 PCT application as prior art to the subject application, which as indicated above was filed on August 27, 1998. The Declaration has been signed by each of the inventors and indicates that on a date prior to August 27, 1998, the Invention was conceived of and reduced to practice in the United States. To evidence conception and reduction to practice of the Invention, attached to the Declaration is an Invention Disclosure including drawings and a description of the Invention which correspond to the subject matter disclosed and claimed in the subject patent application. The dates listed on the Invention Disclosure have been blacked out, as well as dimensional data associated with the Invention. However, the joint inventors have declared that the "Date of Conception" and the "Date Constructed" occurred prior to August 27, 1998. The Declaration also indicates that on a date prior to August 27, 1998 and shortly after the Invention was reduced to practice, the Invention

was tested in the United States. The joint inventors have further declared that the “Date First Tested” listed on the Invention Disclosure occurred prior to August 27, 1998. Following construction and testing of the Invention, the Invention Disclosure was forwarded to the law firm of Woodard, Emhardt, Naughton, Moriarity & McNett for preparation of a patent application. A patent application disclosing and claiming the Invention was filed with the U.S. Patent and Trademark Office on October 28, 1998. (U.S. Patent Application Serial No. 09/181,353; issued as U.S. Patent No. 6,174,311). The subject patent application claims priority back to the parent patent application filed on October 28, 1998.

The Applicant submits that the attached Declaration is effective to remove the ‘769 PCT application as prior art to the subject application. However, the Applicant reserves the right to refute the claim rejections set forth in the Office Action should the Declaration for any reason be deemed ineffective to remove the ‘769 PCT application as prior art.

**Rejection of Claims 217-229, 240-244, 250-258 and 261-270 under 35 U.S.C. §102(e)**

The ‘762 patent is a national stage application stemming from the ‘769 PCT application, which in turn purports to claim priority to the ‘630 parent application as a continuation-in-part application. As indicated above, absent the purported priority claim, the ‘762 patent does not constitute prior art to the subject application. As also indicated above, the ‘769 PCT application has been removed as prior art to the subject application via the filing of the Declaration of Prior Invention. Accordingly, the only subject matter which could possibly be considered to constitute prior art to the subject application is the subject matter disclosed in the ‘630 parent application. A courtesy copy of the as-filed ‘630 parent application is attached hereto.

The Applicants note that the subject matter disclosed in the ‘630 parent application does not include all of the subject matter disclosed in the ‘762 patent. Specifically, the ‘630 parent application does not include Figures 8D-8G and 9-17 and the corresponding portions of the written description, as present in the ‘762 patent. Accordingly, the subject matter disclosed in Figures 8D-8G and 9-17 and the corresponding portions of the written description of the ‘762 patent does not constitute prior art to the subject application. Specifically, the subject matter disclosed in Figures 8D-8G and 9-17 and the corresponding portions of the written description were added to the ‘769 PCT application, which as indicated above has

been removed as prior art to the subject application via the filing of the Declaration of Prior Invention. As a result, the only subject matter which could possibly be considered to constitute prior art to the subject application is the subject matter disclosed in the '630 parent application, which disclosure is limited to Figures 1-7 and 8A-8C and the corresponding portions of the written description. However, the Applicant reserves the right to challenge the subject matter disclosed in the '630 parent application as constituting prior art to the subject application.

The Applicant further notes that the grounds of rejection set forth in the Office Action with regard to the apparatus claims, including independent apparatus claim 217, are based entirely on the subject matter illustrated in Figures 8D-8G and the corresponding portions of the written description. (See pages 2-3 of the Office Action). As indicated above, the subject matter illustrated in Figures 8D-8G and 9-17 and described in the corresponding portions of the written description have been removed as prior art via the Declaration of Prior Invention. Accordingly, the rejections of the apparatus claims are deemed moot and withdrawal of the same is respectfully requested.

Furthermore, the Applicants note that none of the implant embodiments illustrated in Figures 1-7 and 8A-8C include each of the elements and features recited in independent claim 217. Specifically, none of the implant embodiments illustrated in Figures 1-7 and 8A-8C comprise an elongate bone portion formed from a cross-sectional bone slice taken from a diaphysis of a long bone and including opposite first and second end portions, opposite first and second bone engaging surface, a first sidewall including a recessed area defined by a partial portion of the medullary canal of a long bone and defining "a concave outer surface extending along said longitudinal axis between said first and second end portions from said first bone engaging surface to said second bone engaging surface" and a second sidewall arranged generally opposite the first sidewall and including "a convex outer surface extending along said longitudinal axis between said first and second end portions from said first bone engaging surface to said second bone engaging surface", and "wherein said concave outer surface of said first sidewall extends generally parallel with and is positioned opposite said convex outer surface of said second sidewall to provide said elongate bone portion with an elongate crescent-shaped outer cross-section in a plane including said longitudinal axis".

For at least the reasons set forth above, the Applicant submits that independent apparatus claim 217 is patentable over the cited art. Accordingly, withdrawal of the rejection of independent claim 217 and allowance of the same is respectfully requested.

Claims 218-229 and 240-244 depend either directly or indirectly from independent claim 217 and are patentable for at least the reasons supporting the patentability of independent base claim 217. The Applicant further notes that the Office Action does not set forth any grounds whatsoever regarding the subject matter recited in dependent claims 218-229 and 240-244. Indeed, the grounds of rejection set forth in the Office Action with regard to the apparatus claims are directly solely to independent claim 217. Accordingly, the Office Action does not set forth any rationale or reasoning in support of the anticipatory rejections of dependent claims 218-229 and 240-244, and the Applicant submits that the rejection of these claims are therefore improper. Furthermore, many of these dependent claims recite subject matter that is clearly not disclosed or in any way suggested by the Sander reference. The Applicant reserves the right to provide further arguments in support of the patentability of dependent claims 218-229 and 240-244.

Independent method claim 250 has been rejected as being anticipated by Sander. The entire grounds in support of the rejection of independent method claim 250 is set forth on page 3 of the Office Action where an assertion is made that “the method steps, as set forth, would have been inherently carried out in the operation of the device, as set forth above and as set forth in column 14, lines 30-67, column 15, lines 1-40, column 16, lines 1-40; and as best seen in FIGS. 1-17”.

As an initial matter, the Applicant notes that the cited passages of the Sander references (i.e., columns 14-16) were not disclosed in the ‘630 parent application to Sander. Additionally, as indicated above, the ‘763 patent does not qualify as prior art to the subject application (absent its priority claim), and the ‘769 PCT application has been removed as prior art to the subject application via the Declaration of Prior Invention. Accordingly, the rejection of independent method claim 250 is based on subject matter that does not qualify as prior art to the subject application.

Furthermore, the Applicant submits that a single conclusory statement which merely asserts that multiple method steps would have been inherently carried out in the operation of a

device does not establish anticipation. Specifically, in order for an element to be inherently disclosed, it must “necessarily be present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.” In re Robertson, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citing Continental Can Co. v. Monsanto Co., 948 F2d 1264, 1268 (Fed. Cir. 1991)). Furthermore, inherency “may not be established by probabilities or possibilities . . . The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” Id. at 1951. Additionally, “[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art.” Ex parte Levy, 17 USPQ2d 1461, 1464 (USPTO Bd. of Pat. App. and Interferences 1990) (emphasis in the original).

It is respectfully submitted that each of the acts and features recited in independent claim 250 regarding the method of forming a spinal implant are not disclosed in Sander. Additionally, the Office Action does not provide any basis in fact and/or technical reasoning supporting how Sander satisfies the acts and features recited in independent claim 250. Indeed, the brief statement set forth in the Office Action that “the method steps . . . would have been inherently carried out in the operation of the device” is merely conclusory. Accordingly, anticipation has not been established with regard to independent claim 250 and the claims depending therefrom.

Furthermore, independent claim 250 recites the specific steps of “removing a cross-sectional bone slice from the diaphysis of the long bone, the cross-sectional bone slice including an outer cortical bone wall surrounding an inner medullary canal having a length”, “cutting the bone slice along the length of the medullary canal and dividing the bone slice into a plurality of bone slice segments, with each of the bone slice segments including a partial portion of the outer cortical bone wall and a partial portion of the medullary canal”, and “forming an elongate bone portion from one of the plurality of bone slice segments”. Furthermore, the elongate bone portions are recited as including opposite first and second end portion, opposite first and second bone engaging surfaces, a first sidewall including a recessed area disposed between the first and second end portions and defined by the partial portion of the medullary canal and defining a concave outer surface extending along the longitudinal

axis between the first and second end portions from the first bone engaging surface to the second bone engaging surface. Each of these elements, steps and features are not disclosed in Sander.

Although Figures 8B and 8C appear to illustrate that implants may be formed of a bone having a diaphysis, the implants are not formed from a cross-section bone slice via “cutting the bone slice along the length of the medullary canal and dividing the bone slice into a plurality of bone slice segments, with each of the bone slice segments including a partial portion of the outer cortical bone wall and a partial portion of the medullary canal”. Indeed, the implants are formed entirely from the solid portion of the bone, and are not formed by “cutting the bone slice along the length of the medullary canal”, as recited in independent claim 250. Instead, each of the formed implants are outwardly offset from the medullary canal, and therefore do not include any portion of the medullary canal. Furthermore, the implants do not include “a first sidewall including a recessed area . . . defined by the partial portion of the medullary canal and defining a concave outer surface extending along the longitudinal axis between the first and second end portions from the first bone engaging surface to the second bone engaging surface”. Indeed, as indicated above, none of the implants include any portion of the medullary canal, and also fail to define “a concave outer surface extending along the longitudinal axis between the first and second end portions”. Instead, the only portion of the implant that could even arguably define a concave outer surface is the curved end portion of the implant. However, this curved end portion does not include a concave outer surface extending between the first and second end portions, as recited in independent claim 250.

For at least the reasons set forth above, the Applicant submits that independent claim 250 is patentable over the cited art. Accordingly, withdrawal of the rejection of independent claim 250 and allowance of the same is respectfully requested.

Claims 251-270 depend either directly or indirectly from independent claim 250 and are patentable for at least the reasons supporting the patentability of independent base claim 250. The Applicant further notes that the Office Action does not set forth any specific grounds regarding the subject matter recited in dependent claims 251-270. Instead, the Office Action merely asserts that “the method steps, as set forth, would have been inherently carried


out in the operation of the device”. Since the Office Action does not set forth any rational or reasoning in support of the anticipatory rejections of dependent claims 251-270, the Applicants submit that the rejection of these dependent claims is improper. Furthermore, many of these dependent claims recite subject matter that is clearly not disclosed or in any way suggested by the Sander reference. However, the Applicant reserves the right to provide further arguments in support of the patentability of dependent 251-270.



### CONCLUSION

The Applicant respectfully requests entry of this response to the non-final Office Action and consideration and allowance of the present application including pending claims 217-229, 240-244 and 250-270. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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